UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,054	02/27/2004	Nilendu Sen	1276-8	9167

7590 11/01/2006

Michael E. Carmen, Esq.
M. CARMEN & ASSOCIATES, PLLC
Suite 400
170 Old Country Road
Mineola, NY 11501

EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,054	SEN ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *21,23,29-35,37-44,47-54 and 57-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,22,24-28,36,45,46,55,56 and 61-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/14/2004, 9/2/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 10/10/2006 is acknowledged. Claims 1-20, 22, 24-28, 36, 45-46, 55-56, and 61-64 are being examined on their merits herein and Claims 21, 23, 29-35, 37-44, 47-54, and 57-60 are withdrawn from consideration as they do not read on the elected invention or species. The traversal is on the ground(s) that there is not a serious burden on the Examiner to search the inventions of Groups I and II. This is not found persuasive because as is stated in the Election/Restriction requirement dated on 8/24/2006, inventions are distinct if it can be shown that: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). The Examiner pointed out that the process for using the product can be accomplished with another materially different product, such as baclofen as the muscle relaxant, and aspirin as the pain medication. Because the two inventions are distinct, the requirement is still deemed proper and is therefore made **FINAL**.

Priority

This application claims priority to India application 1180/MUM/2003 filed on 11/12/2003. Applicant's priority is acknowledged.

Claim Objections

Claim 45 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 45 depends on a claim that is withdrawn from consideration because it doesn't read on the elected species.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 56, 62, and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clearly defined in the claims or the specification as to what the isomers and derivatives of tizanidine are referring to.

Claim Rejections – 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Faour et al. (WO 02/058620, using EP 1,362,585 as a translation).

Faour et al. teach pharmaceutical compositions containing a COX-II inhibitor, a muscle relaxant and at least one pharmaceutical excipient (meeting the limitations of claims 1 and 4; paragraph 0009). Faour et al. also teach an osmotic device that provides a first composition of a muscle relaxant in the core and an immediate release of a COX-II inhibitor in the coating, meeting the limitation of claims 5-8 in that the coating is in layered arrangement with and surrounds the core and the first composition may be in contact or spaced-away from the second drug composition (and further meeting the limitation of claim 1; Example 3). It is also taught that a semi-permeable membrane surrounds the core (containing the muscle relaxant in Example 3; further meeting the limitation of claim 2; paragraph 0066). A suitable dosage form includes layered or coated tablets (meeting the limitation of claim 3; paragraph 0026).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-20, 22, 24-28, 36, 45-46, and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al. (WO 02/058620, using EP 1,362,585 as a translation).

Faour et al. (WO 02/058620) teaches pharmaceutical compositions containing a COX-II inhibitor and a muscle relaxant for the treatment of pain related disorders such

as muscle pain as discussed in the above rejection. The COX-II inhibitor is independently selected from any of the COX-II inhibitors disclosed in the art and the muscle relaxant is selected from a group that includes tizanidine (meeting the limitations of claims 11-12, 62; paragraph 0010). The pharmaceutical composition provides a slow rate of release over a period including one day (meeting the limitation of claim 61; paragraph 0029). The pharmaceutical composition contains water soluble polymers, such as polyvinyl pyrroldine (meeting the limitation of claims 17-18; paragraph 0059), a hydrophilic pore former, such as mannitol (meeting the limitation of claims 22 and 24; paragraph 0079), ethyl cellulose (meeting the limitation of claims 13-14; paragraph 0081), acrylic resins (further meeting the limitation of claim13 and claims 15-16; paragraph 0065), a lubricant, such as stearic acid (meeting the limitation of claims 36 and 45; paragraph 0087), plasticizers (meeting the limitation of claim 25; paragraph 0095), hydroxypropylmethylcellulose (meeting the limitations of claims 19-20; paragraph 0059), cellulose ethers (meeting the limitations of claims 27-28; paragraph 0066), and pregelatinized starch (meeting the limitation of claim 46; paragraph 0081). Drugs and excipients that comprise the core are mixed to obtain granules and is then compressed into a tablet (meeting the limitation of claim 10; paragraph 0107).

Accordingly, one having ordinary skill in the art would be motivated to add the polyvinyl pyrroldine, mannitol, ethyl cellulose, acrylic resins, stearic acid, plasticizers, hydroxypropylmethylcellulose, cellulose ethers and pregelatinized starch into the pharmaceutical composition comprised of a COX-II inhibitor and muscle relaxant

(Example 3) of Faour et al. to provide a composition with an improved, additive or synergistic analgesic effect that will be effective for an extended period of time.

Claims 55-56, and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al (WO 02/058620) as applied to claims 1-20, 22, 24-28, 36, 45-46, and 61-62 in the above rejections, and in further view of Talley et al., "4-[5-methyl-3-phenyllisoxazol-4-yl]-benzenesulfonamide, valdecoxib: a potent and selective inhibitor of COX-2"; J Med Chem 2000, 43, 775-777.

Faour et al. (WO 02/058620) teaches controlled release formulations comprised of a COX-II inhibitor and a muscle relaxant.

Faour et al. (WO 02/058620) does not teach valdecoxib as the COX-II inhibitor.

Talley et al. teach that valdecoxib is a COX-II selective inhibitor used for the management of pain and inflammation (entire document).

It is further taught by Talley et al. that valdecoxib is an art equivalent COX-II inhibitor to compounds such as celecoxib; therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to formulate a pharmaceutical composition containing valdecoxib as the COX-II inhibitor because Faour et al. teaches a combination pharmaceutical composition comprised of COX-II inhibitors such as celecoxib. Talley et al. further teaches that valdecoxib has greater potency and high specificity for the COX-II receptor compared to other inhibitors; therefore, one having ordinary skill in the art would have been motivated to utilize valdecoxib in the pharmaceutical composition of Faour et al. for an improved anti-inflammatory effect.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER